

REMARKS

RESPONSE TO ELECTION/REQUIREMENT FOR RESTRICTION

The Applicants are required to restrict their invention to one of the following groups. Groups I-XVI are directed to a compound or composition of formula I, according to Claims 67-125. Groups XVII-XXXIII are directed to a method of modulating in vivo activity of a kinase, as in any one of Groups I-XVI, according to Claim 126. Groups XXXIV-XLVIII are directed to a method of treating a disease or disorder, as in any one of Groups I-XVI, according to Claim 127-136. The Applicants further are required to elect a single species for examination on the merits.

The Applicants elect, with traverse, Group VI directed to “the compound or composition of formula (I), according to Claims 67-125 wherein Z is -NH-, R¹ is CH₃, and M¹M²M³M⁴ represents a -CH₂- coupled to a seven-membered or larger nitrogen containing heterocyclic ring.” The Applicants elect the following species: *N*-(3,4-dichloro-2-fluorophenyl)-7-({[(3*aR*,5*r*,6*aS*)-2-methyloctahydrocyclopenta[*c*]pyrrol-5-yl]methyl}oxy)-6-(methyloxy)quinazolin-4-amine, the titled compound of Example 14 on page 120 of the Specification. The elected species is encompassed by pending, currently-amended Claims 67-77 and 84-88, previously-presented Claim 125, and new Claims 142-145, 147, and 148.

The Applicants understand the election to be provisional and that Group VI will be examined with respect to the elected species and if found to be patentable, the examination will be extended to the other Markush group members set forth in Groups VII-XLVIII. To the extent that the Examiner intends that the Applicants amend their generic claims so as to excise the non-elected subject matter (i.e. Groups I-V and VII-XLVIII), then the Applicants respectfully traverse this Restriction Requirement. The Applicants request clarification of the status of the nonelected subject matter and whether it is to be permanently withdrawn from consideration. The Applicants also respectfully request reconsideration of the restriction for the following reasons:

ARGUMENTS

The Applicants respectfully point out that Claims 113-120 are directed to a Compound of Formula Ia, not Formula I. Formula I and Ia cover different scope; and

consequently, there is subject matter in Claims 113-120 which do not fall within any of the restriction groups which groups are all directed to compounds of Formula I. The Applicants also respectfully point out that the compounds claimed in Claims 123, 124, and 154 do not fall within the scope of Formula I or Ia; however these compounds are useful intermediates in the synthesis of a compound of Formula I or Ia. Consequently, these compounds do not fall within any of the restriction groups which are all directed to compounds of Formula I. The Restriction Requirement is incomplete and therefore it is not possible for the Applicants to respond fully.

The Applicants wish to point out that Claims 123, 124, and 154 are directed to intermediates which are useful in the preparation of Compounds of Formula I and Ia. § 1850 of MPEP addresses unity of invention with respect to intermediates and final products.

The Examiner states that the invention does not relate to a single general inventive concept under PCT Rule 13.1 because it “lacks the same or corresponding special technical features” [Restriction Requirement dated September 19, 2007 (hereinafter “Restriction Requirement”), page 5]. Rule 13.1 states that special technical features “...shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art” (emphasis added). More particularly, § 1850 of MPEP addresses unity of invention for chemical compounds in a Markush. For a Markush grouping of alternative chemical compounds, the requirement of a technical interrelationship involving the same or corresponding special technical features are met when the alternatives are of a similar nature. Alternatives are of a similar nature when “(A) [a]ll alternatives have a common property or activity; and (B) (1) [a] common structure is present, i.e., a significant structural element is shared by all of the alternatives...” (*id.*). A shared, significant structural element is met where the “compounds share a common chemical structure which occupies a large portion of their structures” (*id.*). The Applicants submit that the invention meets the above requirements for unity of invention.

The Examiner states that the technical feature linking the claims is a compound of Formula I; however, the Examiner limits the core structure to a N-phenyl-quinazoline-4-amine. PCT 13.2 states that the claimed invention’s contribution over the art is based on

the invention considered as a whole. The Applicants respectfully point out that their invention is defined by Formula I and Ia each of which requires a bicyclic ring-containing group at the 7-position and that "N-phenyl-quinazoline-4-amine" does not define the Applicants' invention as a whole. The Examiner cites *J. Med Chem.* **1996**, 39(1), 267 (Bridges reference) as evidence that there is no special technical feature which defines a contribution over the art. The Applicants respectfully point out that the quinazolines in the cited reference do not have a bicyclic ring-containing group at the 6- or 7-position of the quinazoline and at most have an alkoxy. A requirement of the Applicants' compound of Formula I and Ia is that, in the core structure, there must be a bicyclic ring-containing group at the 7-position. The Applicants respectfully submit that the Examiner has not considered Applicants' invention as a whole.

The Applicants consider the Restriction Requirement to be improper. The particular issue here is whether the U.S.P.T.O. has the authority to compel an applicant to divide up her or his generically claimed invention. The Applicants submit that it does not have this authority. If, in order to comply with the Restriction Requirement, the Applicants are compelled to divide their generically claimed invention into various subgenus claims, the Applicants will not have their claims examined in the form that they believe best to define their invention. Decisions by the Patent and Trademark Office Board of Patent Appeals and its reviewing court clearly hold that a restriction requirement which compels an applicant to divide a generic claim for the purposes of excising non-elected subject matter is improper and that such a procedure amounts to a rejection. To the extent that the Applicants will be required to withdraw non-elected subject matter permanently from consideration, they submit that this is improper.

The proper treatment of the restriction of Markush-type claims is described in § 803.02 of the M.P.E.P. According to that section, the Examiner may require that the Applicants elect a particular species for examination; however, this is a procedural tool and there is nothing found in the statutes, regulations, procedures, or case law which provides that the Applicants must amend the scope of a generic claim to excise non-elected species. This is reiterated in § 809.02(c) of the M.P.E.P.:

An examiner's action subsequent to an election of species should include a complete action on the merits of

all claims readable on the elected species.

....

(B) When a generic claim is subsequently found to be allowable, and not more than a reasonable number of additional species are claimed [in different claims], treatment shall be as follows:

(1) When all claims to each of the additional species are embraced by an allowable generic claim as provided by 37 CFR 1.141, applicant must be advised of the allowable generic claim and that claims drawn to the non-elected species are no longer withdrawn since they are fully embraced by the allowed generic claim.

(Emphasis added.) The Applicants point out the “a reasonable number” of species refers to those *specifically* enumerated by a claim and not to the number of species embraced by the generic claim.

The proper procedure for restriction of a Markush claim is as follows. The examiner may require an applicant to elect provisionally a species for examination. If the elected species is ultimately found patentable, then examination is extended to the provisionally withdrawn subgenera. If a species is examined on the merits and found unpatentable, the examiner then may reject any claims which read on the unpatentable species. This rejection may be overcome by amendment. Thus, the prior art search is not extended unnecessarily and the applicant’s invention, as he or she contemplates it, is examined on the merits. Here, it appears that the Examiner will not examine the non-elected groups and that the non-elected subject matter will be withdrawn permanently from the claims. While it is proper to withdraw non-elected subject matter *provisionally* during an examination of a species, it is improper to withdraw *permanently* from consideration all non-elected species.

To the extent that the Applicants will be required to withdraw non-elected subject matter permanently from consideration, this will include the withdrawal of entire claims that are sub-genuses of the most generic Markush claim, and/or parts of individual claims. The M.P.E.P. does not allow this. Entire claims that are dependent on the most generic claim of the invention are allowed to contain independent and distinct inventions. The Applicants direct the Commissioner to 37 C.F.R. § 1.141 (a):

Two or more independent and distinct inventions may not be claimed in one national application, except that more than one species of an invention, not to exceed a reasonable number, may be specifically claimed in different claims in one national application, provided that the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form (§ 1.75) or otherwise include all the limitations of the generic claim. (Emphasis added.)

In Claims 68-104 and 137-150 the Applicants have claimed species of the generic Claim 67. In Claims 114-120 and 151-153 the Applicants have claimed species of the generic Claim 113. The Applicants make no assertion whether their generic claims contain independent and distinct inventions. Even assuming these species claims represent independent and distinct inventions, they include all of the limitations of the generic claim from which they depend. Written in such a manner, it is entirely proper for the Application to contain species claims that may be independent and distinct.

The Examiner's basis for the Restriction Requirement is that invention as described by the Applicants contains independent or distinct inventions. In particular, the Examiner states that the groups of inventions, as drawn up by the Examiner, "are not so linked as to form a single inventive concept" (Restriction Requirement, page 2), that the various named compounds in Claims 105-112 are "independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species" (*id.* at page 6), that the "species are not obvious variants of each other based on the current record" (*id.*), and that "prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. § 101 and/or 35 U.S.C. § 112, first paragraph" (*id.* at page 7). Applicants contend that whether a Markush claim contains independent or distinct inventions is not the issue and that under restriction practice, Markush claims are allowed to contain independent and distinct inventions.

In particular, § 803.02 of the M.P.E.P. states that Markush Claims are allowed to contain independent and distinct inventions. The Applicants direct the attention of the Examiner to § 803.02 of the M.P.E.P. which states:

A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s).

While making no assertions about the diversity of Markush group members in the claims of this Application, the Applicants submit that § 803.02 specifically allows a Markush claim to contain members that are diverse enough that prior art making one member obvious would not make another obvious. Contrary to the Examiner's discussion of "independent or distinct species" and of the invention containing "groups of inventions," it should be noted that the Applicants consider the Application to contain one invention of which there are different aspects.

In this Application, excising non-elected subject matter will result in withdrawal of subject matter from within the most generic Claims 67 and 113 as well as from within individual claims that depend from generic Claims 67 and 113. Using 35 U.S.C. 121 and 372, the Examiner carved out a subgeneric concept seemingly based on classifications. This practice of withdrawing non-elected subject matter from within a claim has been prohibited by the courts. The Applicants direct the Examiner's attention to *In re Haas*, 486 F.2d 1053 (C.C.P.A. 1973) (*Haas I*) (further proceedings at *In re Haas*, 580 F.2d 461 (C.C.P.A. 1978)). In that case, the examiner, relying on 35 U.S.C. § 121,¹ objected to two Markush claims as each being drawn to multiple patentably distinct inventions and withdrew them both from further consideration. A species claim was allowed and a "narrow Markush claim, encompassing only those reactive moieties similar to the allowed species, was suggested" (*Haas I* at 1054). The applicants were then compelled to cancel the original claims. Limiting the Applicants to certain groups based around the elected species will have the same effect. The *Haas I* court held that an objection of this sort can deny the applicant's substantive rights and amount to a rejection of those claims. The claim would never be examined on the merits, essentially denying the patentability of the invention as the applicants saw fit to claim it. In this Application, it appears the

¹ Section 121 states: "If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions".

Examiner intends to require that all non-elected subject matter that does not fall within the elected group be canceled from the generic claims. This amounts to a rejection of the claims and a denial of substantive rights.

The Court in *In re Weber*, 580 F.2d 455 (C.C.P.A. 1978) addressed this same situation and held that the restriction requirement was improper, stating:

As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

Id. at 458 (emphasis added). The *Weber* court is particularly clear that the division of a single claim by the examiner, with the non-elected subject matter being withdrawn from further consideration, is not permissible. In this Application, the Examiner has required that the Applicants divide their generic claims into multiple parts, denying them an examination of their invention as a whole.

Please see also *Ex parte Holt*, 214 USPQ 381 (Bd. App. 1982) (*Holt I*) (subsequent proceedings at *Ex parte Holt*, 218 U.S.P.Q. 747 (B.P.A.I. 1982) and *Rohm and Haas Company v. Robert Gottschalk, Commissioner of Patents*, 504 F.2d 259 (D.C. Cir.1974) for similar holdings.

By limiting dividing the scope of the invention into forty-eight groups, the Examiner, rather than the Applicants, has defined the form in which the invention is claimed. It is not clear how the Examiner, not knowing the particular facts regarding the invention, determined whether a particular species fell within the same inventive concept as another. An applicant has a right to have each claim examined on the merits in the form she or he considers to best define her or his invention. (See 35 U.S.C. § 112, second paragraph.) The Applicants refer the Examiner to *In re Wolfrum*, 486 F.2d 588, 591

(C.C.P.A. 1973) where the court stated “[u]nder this provision of § 112, the scope of the subject matter is governed not by the examiner’s conception of the ‘invention’ but by that ‘which the applicant regards as his invention.’” *Weber* at 458 also speaks to this issue: “[a]n applicant is given, by the statute, the right to claim his invention with the limitations he regards as necessary to circumscribe that invention.” Here, the Examiner has drafted genres and in doing so defines the invention for the Applicants which is improper.

It appears to the Applicants that the Examiner has created the groups based on classifications. The Applicants respectfully turn the Examiner’s attention to § 1850 of the M.P.E.P. which states that lack of unity of invention should not be raised “merely because the inventions claimed are classified in separate classification groups or merely for the purpose of restricting the international search to certain classification groups.” This is what the Examiner has appeared to do by dividing the Applicants’ composition of matter claims into sixteen different groups.

Finally, the Examiner states that “[t]here is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics” (Restriction Requirement, page 7). The Applicants respectfully point out that the Examiner is not required to examine every species. (Please see M.P.E.P. 803.02 which does not require all claimed species to be examined, only a reasonable number to determine whether the entire genus is allowable.) Even assuming that there is a burden on the Examiner, the Applicants respectfully submit that when there is a conflict between an applicant’s statutory right to claim the subject matter of her or his invention as she or he sees fit and the Patent Office’s power to regulate the workload of its Examiners, the rights of the applicant must prevail. The Applicants are mindful of the Patent Office’s interest in limiting the burden of the examination in each application. The Court in *Weber* recognizing this interest stated, “[e]ven though the statute allows the applicant to claim his invention as he sees fit, it is recognized that the PTO must have some means for controlling such administrative matters as examiner caseloads and the amount of searching done per filing fee.” *Weber* at 458. However, the court went on to state that “... in drawing priorities between the Commissioner as administrator and the applicant as beneficiary of his statutory rights, we conclude that the statutory rights are paramount.”

Id. at 458-459. The Applicants contend that their right to claim generically their invention prevails over any burden, assuming there is one, on the Patent Office.


The Appellants contend that decisions by the PTO Board of Appeals and its reviewing court clearly establish that the Patent Office may not compel the Appellants under the authority of 35 U.S.C. 121 to cancel nonelected subject matter embraced by their generic claims. The Appellants submit that an election of species requirement is merely a procedural tool employed by Patent Office to commence the examination process. Once the subject matter relating to the elected species is found patentable, the remainder of the claimed invention then is examined.

SUMMARY

In view of the foregoing, the Appellants respectfully request reconsideration of the Restriction Requirement. It is believed that a fee in the amount of \$460.00 is required with the submission of this response and for a two-month extension of time. Should additional fees be required to process this submission and any papers attached, the Commissioner is hereby authorized to charge the necessary fees to Deposit Account Number 50-1108.

Respectfully submitted,

December 19, 2007
Date


Janice V. Wade
Attorney for the Applicants
Reg. No. 50,606

Exelixis, Inc.
210 East Grand Avenue
PO Box 511
South San Francisco, CA 94083-0511
Tel. (650) 837-7553 (direct)
Fax: (650) 837-8234